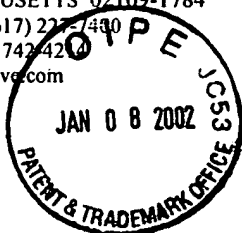


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Commissioner for Patents
Washington, D.C. 20231

December 17, 2001

Re: U.S. Patent Application No.: 09/825,534
*APPARATUS AND METHOD FOR PREDICTION AND MANAGEMENT OF
SUBJECT COMPLIANCE IN CLINICAL RESEARCH*
Inventors: Saul Shiffman et al.
Filed: April 2, 2001
Our Ref. No.: IVQ-001

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form 1449;
3. Copies of references cited in PTO Form 1449; and
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on:

December 17, 2001

Date

David J. Rikkers, Reg. No. 43,882

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

David J. Rikkers
Registration No. 43,882
Attorney for Applicants

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE JAN 11 2002

Technology Center 2100

In re the application of: Saul Shiffman et al.

Serial No.: 09/825,534

Filed: April 2, 2001

For: *APPARATUS AND METHOD FOR
PREDICTION AND MANAGEMENT OF SUBJECT
COMPLIANCE IN CLINICAL RESEARCH*

Attorney Docket No.: IVQ-001

Group Art Unit: 2176

Examiner: Not yet assigned

Commissioner for Patents
Washington, D.C. 20231

Certificate of First Class Mailing (37 CFR §1.8(a))

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Date of Signature and of Mail Deposit

By:



David J. Rikkers

Registration No. 43,882

Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

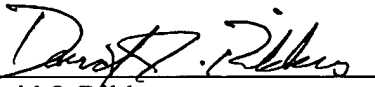
Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

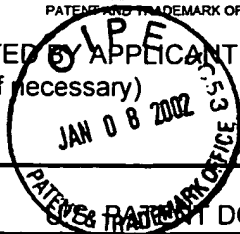

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Enclosures

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LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT Saul Shiffman et al.	RECEIVED JAN 11 2002 Technology Center 2100
		FILING DATE April 2, 2001	



EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	Des. 247,251	02/78	Napoli	D24	17	
	A2	4,262,632	04/81	Hanton et al.	119	1	
	A3	4,353,375	10/82	Colburn et al.	128	782	
	A4	4,367,752	01/83	Jimenez et al.	128	689	
	A5	4,543,955	10/85	Schroepel	128	635	
	A6	4,566,461	01/86	Lubell et al.	128	668	
	A7	4,592,018	05/86	Wiegman	365	63	
	A8	4,686,624	08/87	Blum et al.	364	415	
	A9	4,803,625	02/89	Fu et al.	364	413.03	
	A10	4,844,076	07/89	Lesho et al.	128	631	
	A11	4,883,063	11/89	Bernard et al.	128	670	
	A12	4,909,260	03/90	Salem et al.	128	721	
	A13	4,966,154	10/90	Cooper et al.	128	671	
	A14	4,974,601	12/90	Tranjan et al.	128	696	
	A15	4,975,842	12/90	Darrow et al.	364	413.02	
	A16	4,987,897	01/91	Funke	128	419 PG	
	A17	5,002,064	03/91	Allain et al.	128	710	
	A18	5,063,937	11/91	Ezenwa et al.	128	723	
	A19	5,078,134	01/92	Heilman et al.	128	421	
	A20	5,111,818	05/92	Suzuki et al.	128	644	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	A21	WO 88/02237 A1	04/88	PCT				
	A22	EP 299667 A1	01/89	EPO				
	A23	WO 89/05116 A1	06/89	PCT				
	A24	FR 2686497 A1	07/93	France			Abstr.	
	A25	WO 94/01040 A1	01/94	PCT				
	A26	WO 94/13198 A1	06/94	PCT				
	A27	WO 94/24929 A1	11/94	PCT				

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER:	A28	Bradburn, NM, et al. "Answering Autobiographical Questions: The Impact of Memory and Inference on Surveys" <i>Science</i> 10 Apr 1987;236:157-161
Examiner		Date Considered
Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-80	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO IVQ-001	SERIAL NO. 09/825,534
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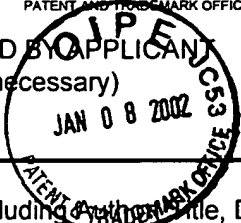
U.S. PATENT DOCUMENTS

B1	5,113,859	05/92	Funk	128	419 PG	
B2	5,128,552	07/92	Fang et al.	307	66	
B3	5,131,390	07/92	Sakaguchi et al.	128	632	
B4	5,137,345	08/92	Waldorf et al.	351	206	
B5	5,181,519	01/93	Bible	128	704	
B6	5,197,489	03/93	Conlan	128	782	
B7	5,199,439	04/93	Zimmerman et al.	128	670	
B8	5,213,106	05/93	Lerner	128	696	
B9	5,213,555	05/93	Hood et al.	482	57	
B10	5,218,969	06/93	Bredesen et al.	128	710	
B11	5,222,503	06/93	Ives et el.	128	731	
B12	5,226,424	07/93	Bible	128	696	
B13	5,226,539	07/93	Cheng	206	534	
B14	5,228,450	07/93	Sellers	128	711	
B15	5,253,654	10/93	Thomas et al.	128	779	
B16	5,261,412	11/93	Butterfield et al.	128	672	
B17	5,271,405	12/93	Boyer et al.	128	672	
B18	5,275,159	01/94	Griebel	128	633	
B19	5,280,429	01/94	Withers	364	413.15	
B20	5,289,824	03/94	Mills et al.	128	696	
B21	5,307,263	04/94	Brown	364	413.09	
B22	5,447,164	09/95	Shaya et al.	128	710	
B23	5,454,376	10/95	Stephens et al.	128	721	
B24	5,672,154	09/97	Sillén et al.	604	50	
B25	5,778,882	07/98	Raymond et al.	128	700	
B26	6,095,985	08/00	Raymond et al.	600	513	

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

B27	Collins, RL, et al. "Ecological momentary assessment in a behavioral drinking moderation training program" <i>Exp. Clin. Psychopharmacol.</i> 1998 Aug;6(3):306-315
B28	Cramer, JA, et al. "How often is medication taken as prescribed?" <i>JAMA</i> 1989 Jun 9;261(22):3273-3277
B29	Eich, E, et al. "Memory for Pain: Relation between Past and Present Pain Intensity" <i>Pain</i> 1985;23:375-380
B30	Friedman, WJ "Memory for the Time of Past Events" <i>Psychological Bulletin</i> 1993;113(1):44-66
Examiner _____ Date Considered _____	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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	GROUP 2176	



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OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

C1	Gorin, AA, et al. "Recall Biases and Cognitive Errors in Retrospective Self-Reports: A Call for Momentary Assessments" <i>Handbook of Heath Psychology</i> . Lawrence Erlbaum Assoc.:Mahwah, New Jersey. 2001;pp. 405-413
C2	Greeno, CG, et al. "Binge antecedents in obese women with and without binge eating disorder" <i>J. Consult. Clin. Psychol.</i> 2000 Feb;68(1):95-102
C3	Hyland, ME, et al. "Diary keeping in asthma: comparison of written and electronic methods" <i>BMJ</i> 20 Feb 1993;306(6876):487-489
C4	Kamarck, TW, et al. "The effects of psychosocial influences on ambulatory blood pressure: contrasting different measurement and data analytic strategies" 37 th Annual Meeting of the Society for Psychophysical Research, N. Falmouth, Massachusetts, USA, Oct. 15-19, 1997. <i>Psychophysiology</i> 1997;34 (Suppl. 1):S6-S7
C5	Kamarck, TW, et al. "Effects of task strain, social conflict, and emotional activation on ambulatory cardiovascular activity: daily life consequences of recurring stress in a multiethnic adult sample" <i>Health Psychol.</i> 1998 Jan;17(1):17-29
C6	Kamarck, TW, et al. "Emotional Support Modrates The Acute Pressor Effects Of Stress During Daily Life" Abstracts of Papers for 1999 Annual Meeting: Paper Session: Cardiovascular Activity in Relation to Stress Psychology and Neurobiology. <i>Psychosomatic Medicine</i> 1999;61(1):112 (abstract)
C7	Kamarck, TW, et al. "The Diary of Ambulatory Behavioral States: A new Approach to the Assessment of Psychosocial Influences on Ambulatory Cardiovascular Activity" <i>Technology and Methods in Behavioral Medicine</i> (D.S. Krantz and A. Baum, eds.) Lawrence Erlbaum Associates:Mahwah, New Jersey. 1998; Chapter 9:163-193
C8	O'Connell, KA, et al. "Overcoming the Urge to Smoke: The Strategies of Long-Term Abstainers and Late Relapsers" <i>Psychology of Addictive Behavior</i> 1991;5(1):1-8
C9	O'Connell, KA, et al. "Coping in real time: using Ecological Momentary Assessment techniques to assess coping with the urge to smoke" <i>Res. Nurs. Health.</i> 1998 Dec;21(6):487-497
C10	O'Connell, KA, et al. "Symptom beliefs and actual blood glucose in type II diabetes" <i>Res. Nurs. Health.</i> 1990 Jun;13(3):145-151
C11	O'Connell, KA, et al. "Reversal theory and smoking: a state-based approach to ex-smokers' highly tempting situations" <i>J. Consult. Clin. Psychol.</i> 1990 Aug;58(4):489-494
C12	O'Connell, KA "Why rational people do irrational things. The theory of psychological reversals" <i>J. Psychosoc. Nurs. Ment. Health Serv.</i> 1991 Jan;29(1):11-14
C13	Paty, J, et al. "The importance of assessing base rates for clinical studes: an example of stimulus control of smoking" <i>The Experience of Psychopathology: Investigating Mental Disorders in their Natural Settings</i> (DeVries, Marten W. ed.) Cambridge University Press:Cambride, England. 1992; pp. 347-352
C14	Penner, LA, et al. "Individual Differences in Intraperson Variability in Mood" <i>Journal of Personality and Social Psychology</i> 1994;66(4):712-721
C15	Potocky, M, et al. "State-outcome consistency in smoking relapse crises: a reversal theory approach" <i>J. Consult. Clin. Psychol.</i> 1991 Apr;59(2):351-353
C16	Raynor, DA ,et al. "The effects of social influence on cardiovascular responsiveness in the natural environment" 37 th Annual Meeting of the Society for Psychophysical Research, N. Falmouth, Massachusetts, USA, Oct. 15-19, 1997. <i>Psychophysiology</i> 1997;34 (Suppl. 1):S73
C17	Ross, M "Relation of Implicit Theories to the Construction of Personal Histories" <i>Psychological Review</i> 1989;96(2):341-357


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		GROUP 2176	

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

D1	Schwartz, JE, et al. "Does trait coping exist? A momentary assessment approach to the evaluation of traits" <i>J. Pers. Soc. Psychol.</i> 1999 Aug;77(2):360-369
D2	Schwartz, JE, et al. "Strategies for analyzing ecological momentary assessment data" <i>Health Psychol.</i> 1998 Jan;17(1):6-16
D3	Shiffman, S. "Real-Time Self-Report of Momentary States in the Natural Environment: Computerized Ecological Momentary Assessment" <i>The Science of Self-Report: Implicates for Research and Practice</i> (A. Stone, et al. eds.) Lawrence Erlbaum Associates: Mahwah, New Jersey. 1989; Chapter 16: 277-296
D4	Shiffman, S. "Assessing Smoking Patterns and Motives" <i>Journal of Consulting and Clinical Psychology</i> 1993;61(5):732-742
D5	Shiffman, S, et al. "Drinking and Smoking: A Field Study of their Association" <i>Annals of Behavioral Medicine</i> 1994;16(3):203-209
D6	Shiffman, S, et al. "Nicotine withdrawal in chippers and regular smokers: subjective and cognitive effects" <i>Health Psychol.</i> 1995 Jul;14(4):301-309
D7	Shiffman, S, et al. "First lapses to smoking: within-subjects analysis of real-time reports" <i>J. Consult. Clin. Psychol.</i> 1996 Apr;64(2):366-379
D8	Shiffman, S, et al. "Progression from a smoking lapse to relapse: prediction from abstinence violation effects, nicotine dependence, and lapse characteristics" <i>J. Consult. Clin. Psychol.</i> 1996 Oct;64(5):993-1002
D9	Shiffman, S, et al. "Temptations to smoke after quitting: a comparison of lapsers and maintainers" <i>Health Psychol.</i> 1996 Nov;15(6):455-461
D10	Shiffman, S, et al. "A day at a time: predicting smoking lapse from daily urge" <i>J. Abnorm. Psychol.</i> 1997 Feb;106(1):104-116
D11	Shiffman, S, et al. "Remember that? A comparison of real-time versus retrospective recall of smoking lapses" <i>J. Consult. Clin. Psychol.</i> 1997 Apr;65(2):292-300
D12	Shiffman, S, et al. "Individual differences in the context of smoking lapse episodes" <i>Addict. Behav.</i> 1997 Nov-Dec;22(6):797-811
D13	Shiffman, S, et al. "The Abstinence Violation Effect Following Smoking Lapses and Temptations" <i>Cognitive Therapy and Research</i> 1997;21(5):497-523
D14	Shiffman, S, et al. "The effect of bupropion on nicotine craving and withdrawal" <i>Psychopharmacology</i> 2000 Jan;148(1):33-40
D15	Shiffman, S, et al. "Dynamic effects of self-efficacy on smoking lapse and relapse" <i>Health Psychol.</i> 2000 Jul;19(4):315-323
D16	Shiffman, S, et al. "Comparative efficacy of 24-hour and 16-hour transdermal nicotine patches for relief of morning craving" <i>Addiction</i> 2000 Aug;95(8):1185-1195
D17	Stone, AA, et al. "Ecological Momentary Assessment (EMA) in Behavioral Medicine" <i>Annals of Behavioral Medicine</i> 1994;16(3):199-202
D18	Stone, AA, et al. "A comparison of coping assessed by ecological momentary assessment and retrospective recall" <i>J. Pers. Soc. Psychol.</i> 1998 Jun;74(6):1670-1680
D19	Stone, AA, et al. "Ecological Momentary Assessment" <i>Well-being: The foundations of Hedonic psychology</i> . Kahneman, Daniel et al. (eds.). Russell Sage Foundation: New York, NY. 1999; pp.26-39

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